

### **510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k091975.

MAR 10 2010

**1. Submitter's Identification:**

Integrated Laboratory Automation Solutions, Inc.  
1223 Chicago Road  
Troy, Michigan 48083

Phone: 248 762 1717

Date Summary Prepared: January 29, 2010

**2. Name of the Device:**

Integrated Laboratory Automation Solution (ILAS)

**3. Common or Usual Name:**

Laboratory Instrument Accessory – Laboratory Automation Software

**Product Codes and Classifications:**

CFR – hexokinase.

Sec. 862.1345 Glucose test system, Class II and JJE analyzer,  
chemistry (photometric, discrete), for clinical use,

Sec. 862.2160 Discrete photometric chemistry analyzer for clinical use, Class I

**4. Predicate Device Information:**

Third Party analyzer examples:

Ortho Clinical Diagnostics Vitros 950 AT Analyzer and Vitros 250 AT  
Automated Analyzer (k922072)

Similar Software: LabInterlink AWCC Software (k010500)

**5. Device Description:**

The automation system (ILAS) is designed to transport clinical patient specimens (blood and urine) to the laboratory analyzers that perform the actual clinical tests.

The ILAS system receives downloads from the Laboratory Information System (LIS) with the patient ID and menu of tests to be performed by the laboratory analyzers. The patients specimens are loaded onto the ILAS and bar codes are read. The bar codes are read at each laboratory analyzer station to determine whether the specimen should be directed to that specific analyzer. If a test is to be run on the analyzer, the specimen is switched to a side track supplying the testing analyzer with clinical specimens. All reporting of clinical specimen test results are transmitted from the analyzer to the LIS and the ILAS software is not involved in test results reporting.

**6. Intended Use:**

The Integrated Laboratory Automation Solution (ILAS) is designed to transport clinical patient samples to clinical laboratory analyzers that perform the actual clinical tests. The ILAS system receives downloads from the Laboratory Information System (LIS) with the patient ID and test orders to be performed by the laboratory analyzer. The patient specimens are loaded onto the ILAS and bar codes are read. The bar codes are read at each analyzer station to determine if tests are to be run and if so the specimen is switched to a side track supplying the analyzer with the specimen.

The ILAS is an accessory to the Vitros 250 automated chemistry analyzer and other similar chemistry automated clinical analyzers. Automated clinical analyzers utilize various methods and technologies for the determination of numerous analytes, such as Glucose and other measurands that may be adaptable to each integrated analyzer.

Glucose on the ILAS system is for the quantitative in vitro diagnostic measurement of Glucose in plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

**7. Technological Characteristics:**

Each of the analyzer products with which the ILIAS may be used, including fluorometers, photometric chemistry analyzers, coagulation timers, and differential cell counters, are analytical instruments intended for use in the analysis of specimens with in vitro diagnostic methods or procedures to determine relevant clinical characteristics of the sample. The ILIAS product, as an accessory to the analyzers, does not change, expand or limit the intended use of each analyzer product. Rather, the software provides a method for automatically providing information to the analyzer that would otherwise be entered manually into the analyzer. The ILIAS does not alter the information, provide different information or provide command or control functions for the

analyzer. Thus, each analyzer's intended use with the ILIAS is identical to its own intended use without the ILIAS.

The technological method by which each analyzer interacts with specimens is inherent to the analyzer and analyte/characteristic being assessed. Use of the ILIAS as an accessory to each analyzer does not alter the principles of operation or technological characteristics of the analyzer.

**8. Performance Data:**

Performance testing performed for each third party analyzer installation includes the analysis of multiple individual analytes tested independently using the third party analyzer with and without the ILIAS interface. This analysis demonstrates that use of the ILIAS with the analyzer produces results that are significantly correlated ( $r \geq 0.999$ ) to the results obtained with the analyzer alone and that the percent difference between results is within the range of analyte interassay variability.

**9. Conclusions:**

Because the ILIAS software product interacts with 510(k) cleared or 510(k) exempt analyzers in a way that does not change the intended use, indications, principles of operation or technological characteristics of the original device, the ILIAS products are accessories to the analyzers that are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Integrated Laboratory Automation Solutions, Inc.  
c/o Maria F Griffin - Official Correspondent  
MDI Consultants, Inc.  
55 Northern Blvd., Suite 200  
Great Neck, NY 11021

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-0609  
Silver Spring, MD 20993-0002

MAR 10 2010

Re: k091975

Trade/Device Name: Integrated Laboratory Automation Solution  
Regulation Number: 21 CFR Sec.- 862.1345  
Regulation Name: Glucose test system.  
Regulatory Class: II  
Product Code: CGA, JJE  
Dated: January 29, 2010  
Received: February 2, 2010

Dear: Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K091975

Device Name: Integrated Laboratory Automation Solution (ILAS)

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Prescription Use X  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
510(k) K091975